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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,672	08/31/2001	Victor E. Vandell	P 0282906	7805
909	7590	09/22/2004	EXAMINER	
PILLSBURY WINTHROP, LLP P.O. BOX 10500 MCLEAN, VA 22102			LAMM, MARINA	
			ART UNIT	PAPER NUMBER

1616
DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/942,672	VANDELL, VICTOR E.	
	Examiner	Art Unit	
	Marina Lamm	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>8/31/01</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-24 are pending in this application filed 8/31/01.

Claim Objections

1. Claims 3 and 24 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 3 does not further limit the subject matter of Claim 2 because the thickener recited in Claim 2 is not required in Claim 3. Claim 24 does not further limit the subject matter of Claim 22 because Claim 22 is directed to a method of desensitizing the scalp and does not recite any hair treatment.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. Claims 3, 12 and 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is viewed as indefinite because of the recitation "said thickener is replaced by water". It is unclear whether Claim 3 requires the presence of **any** thickener at all. For the purpose of examination, Claim 3 has been interpreted as follows: "A formulation according to claim 1 further comprising water."

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Claim 12 is viewed as indefinite because it recites the limitation "said thickener". There is insufficient antecedent basis for this limitation in the claim because claim 1 does not recite a thickener. It appears that Claim 12 should depend from Claim 2 rather than Claim 1. Further, Claim 12 recites the limitation "white petroleum". It is unclear what is meant by "white petroleum". The Examiner is not familiar with such compound(s) and the specification does not define it. Did the Applicant mean "white petrolatum" or "paraffin" by said term? For the purpose of examination, the term "white petroleum" has been interpreted broadly as to include paraffins.

Claim 19 is viewed as indefinite because it recites the limitation "said emulsion". There is insufficient antecedent basis for this limitation in the claim because claim 1 does not recite an emulsion.

Claim 20 is viewed as indefinite because it omits a transitional phrase. It is unclear whether said method consists of, comprises, or consists essentially of the recited steps. Clarification and appropriate correction is required.

Claim 18 is viewed as indefinite because it contains all limitations of Claim 3 rejected for the reasons given above.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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5. Claims 20 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Bass (US 6,066,676).

Bass teaches a method of imparting an anesthetic effect to the skin comprising rubbing a topical composition containing a combination of an antibiotic and an antihistamine, as anesthetic active, into a clean scalp at night and removing the composition each morning. See Abstract; col. 3, Example 1.

Thus, Bass teaches each and every limitation of Claims 20 and 22-24.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kaplan (US 4,052,513) in view of Durbak et al. (US 4,241,048), both supplied by the Applicant.

Kaplan teaches topical emulsions containing 0.5-15% of benzocaine solubilized in water and ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties to the compositions. See col. 1, lines 30-44, 56-60. The compositions of Kaplan may contain polyethylene glycol, polyethylene glycol esters having MW of 200-

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600, thickeners such as xanthan gum, viscosity control agents such as paraffin and other cosmetic materials. See col. 2. The reference does not teach copolymers and plant oils of the instant claims. However, Durbak et al. teach using PVP/hexadecane copolymer of the claimed MW as crystal growth suppressing agent in benzocaine-containing topical compositions. See col. 1, lines 17-41; col. 2. Further, Durbak et al. teach plant oils such as eucalyptus oil (counterirritant) and coconut oil (liquid carrier/emollient). See col. 3, line 22; col. 4, lines 58-59; Examples. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ PVP/hexadecane copolymer. One having ordinary skill in the art would have been motivated to do this to suppress crystal growth of benzocaine and increase the stability of the composition as suggested by Durbak et al. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of Kaplan such that to employ plant oils. One having ordinary skill in the art would have been motivated to do this to obtain counterirritant and/or emollient effect as suggested by Durbak et al.

8. Claims 1, 3-5, 8-11, 13-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1 574 302 in view of Durbak et al. (US 4,241,048).

GB 1 574 302 teaches anesthetic compositions containing solubilized benzocaine, alcohol and polyethylene glycol having MW of 400. See Example. The reference does not teach the claimed copolymers and plant oils. However, Durbak et al. teach using

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PVP/hexadecane copolymer of the claimed MW as crystal growth suppressing agent is benzocaine-containing topical compositions. See col. 1, lines 17-41; col. 2. Further, Durbak et al. teach plant oils such as eucalyptus oil (counterirritant) and coconut oil (liquid carrier/emollient). See col. 3, line 22; col. 4, lines 58-59; Examples. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of GB 1 574 302 such that to employ PVP/hexadecane copolymer as an additional crystal growth suppressing agent. One having ordinary skill in the art would have been motivated to do this to increase the stability of the composition as suggested by Durbak et al. Further, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the compositions of GB 1 574 302 such that to employ plant oils. One having ordinary skill in the art would have been motivated to do this to obtain counterirritant and/or emollient effect as suggested by Durbak et al.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB 1 574 302 in view of Durbak et al. (US 4,241,048) and further in view of Kaplan (US 4,052,513).

GB 1 574 302 in view of Durbak et al. applied as above. Neither reference teaches the solubilizing agents of the instant claims. However, Kaplan teaches ester solubilizers of the instant invention. See Abstract; col. 1, lines 45-60. These solubilizers are used in concentration of 5-40% and impart desirable emollient properties to the compositions. See col. 1, lines 30-44, 56-60. Therefore, it would have been obvious to

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one having ordinary skill in the art at the time the invention was made to modify the compositions of GB 1 574 302 such that to employ ester solubilizers. One having ordinary skill in the art would have been motivated to do this to solubilize benzocaine and provide emollient properties to the composition.

Conclusion

10. No claim is allowed at this time.

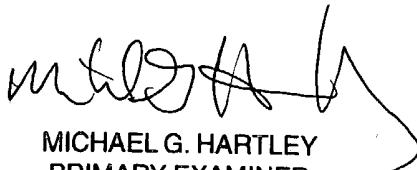
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Lamm whose telephone number is (571) 272-0618. The examiner can normally be reached on Mon-Fri from 11am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ML
9/19/04


MICHAEL G. HARTLEY
PRIMARY EXAMINER